

CERTIFICATE

Biocompatibility Test

Material tested

HITEX

Dental ceramic, EN ISO 9693 and EN ISO 6872

Composition

Silicate glass-ceramic, pigments

Manufacturer

Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13
75179 Pforzheim, Germany

Tests

We confirm that the following tests for determining the biocompatibility were carried out in accordance with the international standards EN ISO 10993, "Biological evaluation of medical devices" (EN ISO 10993-1, EN ISO 10993-2, EN ISO 10993-5, EN ISO 10993-12) and EN ISO 7405: 1997, „Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials“.

The tests were performed according to the OECD directives "Good Laboratory Practice" (GLP) by the Institute BSL Bioservice Scientific Laboratories.

The tests were coordinated and monitored by Dr. Henning, Dental Engineering.

The test items of incisal, dentine and opaque HITEX ceramic were produced by a commercial dental laboratory according to the instructions of the manufacturer.

Cytotoxicity

The cytotoxic potential of the dental ceramic was tested in vitro with L-929 fibroblasts.

Method: "Test on extracts", XTT staining, ISO 10993-5: 1999, EN ISO 10993-12: 2002 and EN ISO 7405: 1997 (5.4.a) 3).

Test result

HITEX had no cytotoxic potential

Dr. G. Henning, Dental Engineering
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Basle, September 26, 2006